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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/518,020	03/03/2000	David L. Kaplan	1322.1026001	5518

21005 7590 07/30/2003

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EXAMINER
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ZEMAN, ROBERT A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 07/30/2003

20

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/518,020	KAPLAN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 02 June 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-3,5-13 and 38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-3, 5-12 and 38 is/are rejected.
- 7) Claim(s) 13 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_ .
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                               | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ .                                   |

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## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6-2-2003 has been entered.

The amendment and response filed on 6-2-2003 are acknowledged. Claims 1-3, 5-11 and 38 have been amended. Claims 4 and 14-37 have been canceled. Claims 1-13 and 38 are pending and currently under examination.

### ***Claim Objections Maintained***

The objection to claim 13 for being dependent on rejected claims is maintained for reasons of record.

### ***Claim Rejections Withdrawn***

The rejection of claims 1-13 and 38 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term "analog" is withdrawn in light of the amendment thereto.

***Claim Rejections Maintained***

***35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-3, 5-11 and 38 under 35 U.S.C. 102(b) as being anticipated by Gutnick et al. (U.S. Patent 4,311,829) is maintained for reasons of record.

**Applicant argues:**

1. The amended claims recite the limitation “emulsan adjuvant”. Gutnick et al. does not disclose or suggest a formulation wherein the emulsan component is an adjuvant.

Applicant’s arguments have been fully considered and deemed non-persuasive.

The instant claims are drawn to formulations comprising an emulsan and an antigen. Gutnick et al. disclose formulations comprising emulsans and Freund’s complete adjuvant. Since Freund’s complete adjuvant comprises *Mycobacterium tuberculosis* constitutes an antigen as defined by the specification (see page 8, lines 1-23). The recited limitation “emulsan adjuvant” is interpreted as an intended use and therefore is given no patentable weight. Since all the rejected claims are drawn to compositions comprising the same components as those compositions disclosed by Gutnick et al., they would, in absence of evidence to the contrary, possess the same

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chemical and immunological properties. Hence, the formulations disclosed by Gutnick et al. anticipate all the limitations of the instant claims.

***35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 1 and 12 under 35 U.S.C. 103(a) as being unpatentable over Gutnick et al. (U.S. Patent 4,311,829) in view of Fino (U.S. Patent 5,464,746) is maintained for reasons of record.

**Applicant argues:**

1. For reasons outline above, Gutnick et al. does not teach or suggest an immunization formulation that includes an emulsan adjuvant.

2. Fino does not remedy the deficiencies of Gutnick et al. since Fino does not teach or suggest an immunization formulation that includes an emulsan adjuvant.

Applicant's arguments have been fully considered and deemed non-persuasive.

The instant claims are drawn to compositions comprising an antigen (either viral, bacterial, parasitic or fungal) and an emulsan. Gutnick et al. disclose formulations comprising emulsans and Freund's complete adjuvant. Since Freund's complete adjuvant comprises *Mycobacterium tuberculosis* constitutes an antigen as defined by the specification (see page 8, lines 1-23). The recited limitation "emulsan adjuvant" is interpreted as an intended use and therefore is given no patentable weight. Since all the rejected claims are drawn to compositions comprising the same components as those compositions disclosed by Gutnick et al., they would, in absence of evidence to the contrary, posses the same chemical and immunological properties. Since the combination of the cited references discloses a composition with said components the rejection is maintained.

### ***Conclusion***

No claim is allowed.

Claims 1-3, 5-12 and 38 are rejected.

Claim 13 is objected to as being dependent on rejected claims.

Claim 13 is free of the art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 608-7991. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Robert A. Zeman  
July 29, 2003